USDA

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United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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Ms. Mary C. Till
Legal Advisor
Commissioner for Patents
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, VA 22313-1450

Dear Ms. Till:

This is in response to your letter of June 12, 2007, regarding the application for patent term extension for U.S. Patent No. 5,510,106 filed by the Regents of the University of California, under 35 U.S.C. section 156 *et seq*. The veterinary biologic product claimed by the patent is Fel-O-Vax® LvK/FIV vaccine (Feline Immunodeficiency-Leukemia Virus Vaccine, Killed Virus), which was assigned VS Code No. 15D5.R0 by the Center for Veterinary Biologics (CVB). The product is manufactured by Wyeth, through its operating subsidiary Fort Dodge Laboratories, Inc. (U.S. Veterinary License No. 112).

We have reviewed the dates contained in the application and have determined the total regulatory review period for Fel-O-Vax® LvK/FIV vaccine to be 1348 days. Of this time, 0 days occurred during the testing phase and 1348 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an Application for a U.S. Veterinary Biological Product License for Fel-O-Vax® LvK/FIV vaccine was submitted to the USDA for approval under the Virus-Serum-Toxin Act: October 15, 1999.

   CVB has verified the applicant's claim that an Application for a U.S. Veterinary Biological Product License for Fel-O-Vax® LvK/FIV vaccine was submitted to the USDA on October 15, 1999. The date the first application for a U.S. veterinary biological product license was submitted to USDA is an appropriate date to recognize when "authorization to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective" [9 CFR section 124.20(a)(1)], because it marks the first official step towards licensure.

2. The date the application was approved and a license issued: June 23, 2003.

   CVB has verified the applicant's claim that Fel-O-Vax® LvK/FIV vaccine was approved and a license issued on June 23, 2003.

This determination of the regulatory review period by CVB does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

It is expected that within the next three months a *Federal Register* Notice will be published regarding the determination of the regulatory review period for purposes of this patent extension. The Notice will provide that on or before 180 days after the publication of the determination, a person can file a petition with the CVB under 35 U.S.C. §156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period. Should no petition be received during that period, the CVB will consider the regulatory review period determination to be final and notify you accordingly.

Please let me know if I can be of further assistance.

Sincerely,

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics